



[Billing Code: 6750-01S]

FEDERAL TRADE COMMISSION

16 CFR Part 315

Contact Lens Rule

AGENCY: Federal Trade Commission (“FTC” or “Commission”).

ACTION: Request for comment.

SUMMARY: The Commission is requesting public comments on the Contact Lens Rule, which requires that eyecare prescribers provide a copy of a consumer’s prescription to the consumer upon completion of a contact lens fitting and verify or provide prescriptions to authorized third parties. The Rule also mandates that a contact lens seller may sell contact lenses only in accordance with a prescription that the seller either: (a) has received from the patient or prescriber; or (b) has verified through direct communication with the prescriber. The Commission is soliciting comments about the efficiency, costs, benefits, and regulatory impact of the Rule as part of its systematic review of all current Commission regulations and guides. All interested persons are hereby given notice of the opportunity to submit written data, views, and arguments concerning the Rule.

DATES: Written comments must be received on or before October 26, 2015.

ADDRESSES: Interested parties may file a comment at

<https://ftcpublishcommentworks.com/ftc/contactlensrule> online or on paper, by following the instructions in the Instructions for Submitting Comments part of the **SUPPLEMENTARY INFORMATION** section below. Write “Contact Lens Rule, 16 CFR part 315, Project No.

R511995” on your comment, and file your comment online at <https://ftcpublic.commentworks.com/ftc/contactlensrule> by following the instructions on the web-based form. If you prefer to file your comment on paper, write “Contact Lens Rule, 16 CFR part 315, Project No. R511995” on your comment and on the envelope and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex C), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex C), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Alysa Bernstein, Attorney, (202) 326-3289, or Bonnie McGregor, Federal Trade Investigator, (202) 326-2356, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Background

In 2003, Congress enacted The Fairness to Contact Lens Consumers Act, 15 U.S.C. 7601-7610, and pursuant to the Act, the Commission promulgated the Contact Lens Rule on July 2, 2004.¹ The Rule went into effect on August 2, 2004.

The Contact Lens Rule is intended to facilitate the ability of consumers to comparison shop for contact lenses while ensuring that contact lenses are sold only in accordance with a valid prescription. The Rule requires that eyecare prescribers provide a copy of a prescription to the consumer upon completion of a contact lens fitting and verify or provide prescriptions to

¹ Contact Lens Rule, 16 CFR part 315.

authorized third parties.²

The Rule specifies that a prescriber may not require the purchase of contact lenses as a condition of providing the prescription or verification, may not require payment in addition to, or as a part of, the fee for an eye examination, fitting, and evaluation as a condition of providing the prescription or verification, and may not require the patient to sign a waiver or release as a condition of releasing or verifying the prescription.³ The prescriber is also prohibited from requiring immediate payment before the release of a prescription, unless the prescriber requires immediate payment when an exam reveals that the consumer does not need ophthalmic goods.⁴

The Rule also places certain restrictions on sellers. It mandates that sellers sell contact lenses only in accordance with a prescription that is either presented to the seller or verified by direct communication with the prescriber.⁵ The Rule sets out the information that must be included in a seller's verification request, and directs that a prescription is only verified under the Rule if: (1) a prescriber confirms the prescription is accurate, (2) a prescriber informs the seller that the prescription is inaccurate and provides an accurate prescription, or (3) if the prescriber fails to communicate with the seller within eight business hours after receiving a compliant verification request.⁶ The Rule states that if the prescriber informs the seller within eight hours of receiving the verification request that the prescription is inaccurate, expired, or invalid, the

² 16 CFR 315.3(a).

³ 16 CFR 315.3(b).

⁴ 16 CFR 315.4.

⁵ 16 CFR 315.5(a).

⁶ 16 CFR 315.5(b)-(c).

seller shall not fill the prescription.⁷

Sellers may not alter a prescription, but for private label contact lenses, may substitute identical contact lenses that the same company manufactures and sells under a different name.⁸ Sellers and others involved in the manufacture, assembly, processing and distribution of contact lenses are prohibited from representing that contact lenses may be obtained without a prescription.⁹

The Contact Lens Rule sets a minimum expiration date of one year after the issue date of a prescription with an exception based on a patient's ocular health.¹⁰ The Rule also implements the Act by providing that "state and local laws and regulations that establish a prescription expiration date of less than one year or that restrict prescription release or require active verification are pre-empted."¹¹

II. Regulatory Review of the Contact Lens Rule

The Commission periodically reviews all of its rules and guides. These reviews seek information about the costs and benefits of the agency's rules and guides, and their regulatory and economic impact. The information obtained assists the Commission in identifying those

⁷ 16 CFR 315.5(d). If the prescription communicated by the seller is inaccurate, the prescriber shall correct it. *Id.*

⁸ 16 CFR 315.5(e).

⁹ 16 CFR 315.7.

¹⁰ 16 CFR 315.6.

¹¹ 16 CFR 315.11(a). The Rule states further that "[a]ny other state or local laws or regulations that are inconsistent with the Act or this part are preempted to the extent of the inconsistency." 16 CFR 315.11(b).

rules and guides that warrant modification or rescission. Therefore, the Commission solicits comments on, among other things, the economic impact and benefits of the Rule; possible conflict between the Rule and State, local, or other Federal laws or regulations; and the effect on the Rule of any technological, economic, or other industry changes since the Rule was promulgated.

III. Issues for Comment

The Commission requests written comment on any or all of the following questions. These questions are designed to assist the public and should not be construed as a limitation on the issues on which public comment may be submitted. The Commission requests that responses to its questions be as specific as possible, including a reference to the question being answered, and reference to empirical data or other evidence upon which comments are based wherever available and appropriate.

1. Is there a continuing need for the Rule? Why or why not?
2. What benefits has the Rule provided to consumers? What evidence supports the asserted benefits?
3. What modifications, if any, should be made to the Rule to increase its benefits to consumers?
 - a. What evidence supports the proposed modifications?
 - b. How would these modifications affect the costs the Rule imposes on businesses, including small businesses?
 - c. How would these modifications affect the benefits to consumers?
4. What impact has the Rule had on the flow of truthful information to consumers and on the flow of deceptive information to consumers?

5. What significant costs, if any, has the Rule imposed on consumers? What evidence supports the asserted costs?
6. What modifications, if any, should be made to the Rule to reduce any costs imposed on consumers?
 - a. What evidence supports the proposed modifications?
 - b. How would these modifications affect the benefits provided by the Rule?
7. What benefits, if any, has the Rule provided to businesses, including small businesses? What evidence supports the asserted benefits?
8. What modifications, if any, should be made to the Rule to increase its benefits to businesses, including small businesses?
 - a. What evidence supports the proposed modifications?
 - b. How would these modifications affect the costs the Rule imposes on businesses, including small businesses?
 - c. How would these modifications affect the benefits to consumers?
9. What significant costs, if any, including costs of compliance, has the Rule imposed on businesses, including small businesses? What evidence supports the asserted costs?
10. What modifications, if any, should be made to the Rule to reduce the costs imposed on businesses, including small businesses?
 - a. What evidence supports the proposed modifications?
 - b. How would these modifications affect the benefits provided by the Rule?
11. What evidence is available concerning the degree of industry compliance with the Rule?

12. What modifications, if any, should be made to the Rule to account for changes in relevant technology or economic conditions? What evidence supports the proposed modifications?

13. Does the Rule overlap or conflict with other federal, state, or local laws or regulations? If so, how?

a. What evidence supports the asserted conflicts?

b. With reference to the asserted conflicts, should the Rule be modified? If so, why, and how? If not, why not?

IV. Instructions for Submitting Comments

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before October 26, 2015. Write “Contact Lens Rule, 16 CFR part 315, Project No. R511995” on the comment. Your comment, including your name and your state, will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission website, at <http://www.ftc.gov/os/publiccomments.shtml>. As a matter of discretion, the Commission tries to remove individuals’ home contact information from comments before placing them on the Commission website. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as a Social Security number, date of birth, driver’s license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information.

In addition, do not include any “[t]rade secret or any commercial or financial information

which is . . . privileged or confidential,” as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you must follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comments to be withheld from the public record. Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comment online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/contactlensrule> by following the instructions on the web-based form. If this document appears at <http://www.regulations.gov/#!home>, you also may file a comment through that website.

If you file your comment on paper, write “Contact Lens Rule, 16 CFR part 315, Project No. R511995” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex C), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex C), Washington, DC 20024.

Visit the Commission website at <http://www.ftc.gov> to read this document and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 26, 2015. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

By direction of the Commission.

Donald S. Clark
Secretary.

[FR Doc. 2015-21577 Filed: 9/2/2015 08:45 am; Publication Date: 9/3/2015]